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10/631,052	07/29/2003	Albert N. Santilli	KSI-11720-I	9276

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EXAMINER	
BLATT, ERIC D	

ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,052	SANTILLI, ALBERT N.	
	Examiner	Art Unit	
	Eric Blatt	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30* is/are allowed.

6)☒ Claim(s) *14-16 and 18-26* is/are rejected.

7)☐ Claim(s) *17 and 27-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-15 and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donlon et al. (US 5,618,307) in view of Sasaki (US 5,081,811).

Regarding claims 14-15, Donlon discloses an aorta cross clamp assembly (Figures 25-27) comprising:

- a clamp having first 308B and second jaws 310B that are movable toward and away from each other;
- an elongate housing 346B having first and second ends, the clamp being connected to the first end;
- an elongate actuator 378 disposed within the housing and operatively connected to the jaws such that axial movement of the actuator within the housing causes the jaws to move toward or away from each other;
- a retainer 324B disposed within the housing,
- a handle 394 connected to the second end of the housing;

- and a stem 380 connected to the actuator, the stem projecting outwardly of the handle, the stem permitting the user to operate the actuator in either the first or second modes of operation permitted by the retainer; and

- the first jaw is fixed and the second jaw is movable toward or away from the first jaw.

This embodiment shown in Figures 25-27 of Donlon does not disclose:

- the retainer having two modes of operation, the retainer in the first mode permitting the actuator to move within the housing such that the jaws are moved toward each other but not away from each other, and the retainer in the second mode permitting the actuator to be moved within the housing such that the jaws are moved away from each other;

The clamp embodiment shown in Figures 25-27 is actuated only by rotating the inner actuating member 378 relative to the housing 346B. In Figures 17-22, however, Donlon discloses a similar remote clamping apparatus that has two modes of operation wherein a retainer 342 has two modes of operation such that the retainer in the first mode permits the actuator to move within the housing such that jaws are moved toward each other but not away from each other, and the retainer in the second mode permits the actuator to be moved within the housing such that the jaws are moved away from each other. Both embodiments have the benefit of being locked in the clamped configuration until the user chooses to release the lock, but the embodiment of Figures 17-22 has the additional advantage of being more quickly and easily manipulated into the clamped configuration. Although this property would be desirable in the embodiment of Figures 25-27, the particular ratcheting locking mechanism of Figures 17-22 would not combine well with the threaded actuating mechanism of Figures 25-27. Sasaki discloses a retaining element 11 that is a nut with a slot therethrough which allows a threaded member to be quickly and easily pushed axially through said retainer in one direction but requires that the threaded member must be rotated relative to the retainer to move it axially in the second direction. (Column 4, Lines 47-59) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Donlon (Figures 25-27) by providing the retainer of Sasaki in order to allow the clamp to be quickly and easily moved into

the clamped configuration and then locked in said clamped configuration as taught by Donlon (Figures 17-22) and Sasaki.

Regarding claims 18 and 23, the embodiment shown in Figures 25-27 of Donlon does not disclose:

- the housing is flexible and the actuator is a cable.

This clamp is designed to reach its target site in the body linearly and thus does not require flexible components. (Figure 23) The embodiment shown in Figures 7-9 of Donlon has a flexible housing and inner member so that it may curve to approach its target site. (Column 9, Line 53 through Column 10, Line 15) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus shown in Figures 25-27 by making the housing and the actuator flexible as taught by the embodiment shown in Figures 7-9 of Donlon for purposes such as allowing the device to curve to approach its target site. The modified actuator 378 is a cable.

Regarding claims 19 and 24, Donlon additionally discloses:

- the second end of the housing includes a fitting to which the handle is secured, and the stem has a knob. (Figure 25, Column 16, Lines 1-23)

Thus, the embodiment shown in Figures 25-27 of Donlon discloses all elements of claim 19 except:

- the handle has a pair of finger loops.

Donlon states that although the handle 280 is shown as a disc, it may also be any other conventional hand grip. (Column 16, Lines 20-23) In Figure 1, Donlon shows a handle having a pair of finger loops. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Donlon (Figures 25-27) by providing a pair of finger

loops as taught by the embodiment shown in Figure 1 since this handle was a known alternative and would have produced expected results.

Regarding claims 20 and 25, the retainer (modified as taught by Sasaki) in the first mode permits the actuator to move axially but not rotationally within the housing such that the jaws are moved toward each other but not away from each other, and the retainer in the second mode permits the actuator to be moved rotationally and axially within the housing such that the jaws are moved away from each other.

Regarding claim 21, Donlon discloses:

- a screw 320B having first and second ends, the first end of the screw being operatively connected to the jaws and the second end of the screw being operatively connected to the actuator; and
- a nut (as taught by Sasaki), the screw passing through the nut, the connection between the nut and the screw being such that the screw can move toward the second jaw without rotating but the screw can move away from the second jaw only by being rotated.

Regarding claim 22, Donlon additionally discloses:

- the screw is operatively connected to the second jaw.

Regarding claim 26, Donlon additionally discloses:

- a base 324B having a bore therethrough; a slot in the first jaw, the second jaw being disposed within the slot; and a hinge pin 316B extending through the slot and the second jaw to support the second jaw for pivotal movement within the slot.

- the first jaw being connected to the base. Since the jaws are threadingly coupled to the base, the first jaw is broadly considered to be connected to the base.

Claim 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donlon et al. (US 5,618,307) in view of Sasaki (US 5,081,811) as applied to claims 14-15 above, and further in view of Hasson (US 5,211,655).

Regarding claim 16, Donlon additionally discloses:

- a base 324B having a bore therethrough; a slot in the first jaw, the second jaw being disposed within the slot; and a hinge pin 316B extending through the slot and the second jaw to support the second jaw for pivotal movement within the slot.
- the first jaw being connected to the base. Since the jaws are threadingly coupled to the base, the first jaw is broadly considered to be connected to the base.

Allowable Subject Matter

Claims 17 and 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30 is allowed.

Response to Arguments

Applicant's arguments, filed February 11, 2008, with respect to claim 17 have been fully considered and are persuasive. The rejection of claim 17 has been withdrawn.

Applicant's arguments with respect to claims 14-16, 18, and 19 have been fully considered but they are not persuasive.

Applicant contends that the rejections of claims 14-16, 18, and 19 have relied on as many as six references, arguing that "although the examiner's use of six references is not dispositive of the unobviousness of the present invention, nevertheless it strongly suggests that the invention in fact would not have been obvious to one skilled in the art." In response, the Examiner notes that there is not a formal upper limit on how many references may be combined in order to reject a claim. The Examiner also points to the fact that only two references were used for said rejections--specifically, a clamp of Donlon et al. was combined with the nut of Sasaki. A second clamp embodiment disclosed in Donlon is additionally to better illustrate a motivation for this combination, but no elements from this second embodiment are used in the combination itself. Thus, Applicant's allegation of combining six references to form these rejections is clearly false.

Applicant further argues that since Sasaki is classified in Class 52, Static Structures, and the claimed invention is classified in Class 606, Surgery, "one skilled in the art of designing aorta cross clamp assemblies would not have been motivated to look to static structures in order to find a teaching of a retainer having two modes of operation." In response, the Examiner notes that the obviousness of employing the teachings of a reference is not dependent upon the location or classification of said reference. As previously discussed in the body of the rejection, the teachings of Sasaki are relevant to improving the function of the clamp of Donlon, and thus, this combination is proper.

Applicant additionally argues that "if it would have been obvious to make the threaded embodiment fast acting, then Donlon and his co-inventors seemingly would have been the ones to do so." The fact that Donlon and his co-inventors did not explicitly disclose that said threaded embodiment is capable of being modified to become fast acting within the specification of US Patent No. 5,618,307 does not show that such a modification would not have been obvious.

Regarding Applicants arguments concerning claim 16, upon further consideration, the first jaw of Donlon may be broadly considered to be connected to the base. The jaws do not rotate with the housing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Todd E Manahan/
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